



METAPHARMACEUTICAL

N DE LOTE:

0080222

CERTIFICATE OF ANALYSIS

10/02/2022

Product : **Prilocaine EP**
 Batch No. : API/PRB/211048
 Date of Mfg. : Sep.2021
 Date of Exp. : Aug.2026
 Manufacturer : Gufic Biosciences Limited.
 Testing Specification No : SPC/FPR/BD/003

QC Ref. No. : QC-FP-API-21-0530
 Quantity Received : 140 Kg.
 Sampling Date : 03/10/2021
 Release Date : 06/10/2021
 Quantity Sampled : 25 gm.
 Specification : EP

TESTS	RESULTS	LIMITS
Appearance	White crystalline powder.	White or almost white, crystalline powder.
Solubility	Slightly soluble in water, very soluble in acetone and in ethanol (96 per cent).	Slightly soluble in water, very soluble in acetone and in ethanol (96 per cent).
Identification By Infrared Spectrophotometry	An IR spectrum of sample is concordant with the standard spectra of working standard of Prilocaine.	An IR spectrum of sample should be concordant with the standard spectra of working standard or reference standard of Prilocaine.
Appearance of solution	Solution is clear and colourless	Solution should be clear and colourless.
Related substances	Impurity B 31 ppm Impurity G 0.00% Unspecified impurity 0.00% Total impurities 0.00%	Not more than 100 ppm Not more than 0.15% Not more than 0.10% Not more than 0.2%
Water	0.06%	Not more than 0.5%
Sulphated Ash	0.03%	Not more than 0.1 %
Assay (Anhydrous Substance)	99.41%	Not less than 99.0% and not more than 101.0%
Residual solvent	Petroleum Ether 8 ppm Acetone 0 ppm Dichloromethane 0 ppm Toluene 0 ppm	NMT 1200 ppm NMT 5000 ppm NMT 600 ppm NMT 890 ppm

REMARK: This is to certify that above product Complies/ ~~Does not comply~~ with prescribed standard quality of EP 10.0.

PREPARED BY
 Name : Mr. Mitul Naik
 Designation : Assistant
 Date : 02/12/2021

CHECKED BY
 Name : Mr. Anand Desai
 Designation : Executive
 Date : 02/12/2021

APPROVED BY
 Name : Mr. Nimesh Pancholi
 Designation : AGM-QC
 Date : 02/12/2021

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